What is claimed is:

1. A suberoylanilide hydroxamic acid (SAHA) Form I characterized by an X-ray diffraction pattern substantially similar to that set forth in Figure 13A.

2. A suberoylanilide hydroxamic acid (SAHA) Form I characterized by an X-ray diffraction pattern including characteristic peaks at about 9.0, 9.4, 17.5, 19.4, 20.0, 24.0, 24.4, 24.8, 25.0, 28.0, and 43.3 degrees 2θ.

3. A suberoylanilide hydroxamic acid (SAHA) Form I characterized by an X-ray diffraction pattern including characteristic peaks at about 9.0, 9.4, 17.5, 19.4, 20.0, 24.0, 24.4, 24.8, 25.0, 28.0, 43.3 degrees 2θ, and lacking at least one peak at about <8.7, 10.0-10.2, 13.4-14.0, 15.0-15.2, 17.5-19.0, 20.1-20.3, 21.1-21.3, 22.0.-22.22, 22.7-23.0, 25.0-25.5, 26.0-26.2, and 27.4-27.6 degrees 2θ.

4. A suberoylanilide hydroxamic acid (SAHA) Form I characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

5. The SAHA Form I according to claim 1, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

6. The SAHA Form I according to claim 2, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

7. The SAHA Form I according to claim 3, further characterized a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

8. A suberoylanilide hydroxamic acid (SAHA) Form I produced by a purification process comprising the step of recrystallizing a crude preparation of SAHA from an organic solvent or a mixture of an organic solvent and water, with the proviso that the use of acetonitrile alone is excluded.

9. The SAHA Form I according to claim 8, further characterized by an X-ray diffraction pattern substantially similar to that set forth in Figure 13A.

10. The SAHA Form I according to claim 8, further characterized by an X-ray diffraction pattern including characteristic peaks at about 9.0, 9.4, 17.5, 19.4, 20.0, 24.0, 24.4, 24.8, 25.0, 28.0, and 43.3 degrees 2θ.

11. The SAHA Form I according to claim 8, further characterized by an X-ray diffraction pattern including characteristic peaks at about 9.0, 9.4, 17.5, 19.4, 20.0, 24.0, 24.4, 24.8, 25.0, 28.0, 43.3 degrees 2θ, and lacking at least one peak at about <8.7, 10.0-10.2, 13.4-14.0, 15.0-15.2, 17.5-19.0, 20.1-20.3, 21.1-21.3, 22.0.-22.22, 22.7-23.0, 25.0-25.5, 26.0-26.2, and 27.4-27.6 degrees 2θ.

12. The SAHA Form I according to claim 8, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

13. The SAHA Form I according to claim 9, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

14. The SAHA Form I according to claim 10, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

15. The SAHA Form I according to claim 11, further characterized by a Differential Scanning Calorimetry (DSC) thermogram having a single maximum value at about 164.4±2.0, as measured by a Perkins Elmer DSC 6 Instrument.

16. The SAHA Form I according to claim 8, wherein said organic solvent is an alcohol.

17. The SAHA Form I according to claim 16, wherein said alcohol is methanol, ethanol or isopropanol.

18. The SAHA Form I according to claim 8, wherein said purification process comprises the step of recrystallizing said crude SAHA from an organic solvent.

19. The SAHA Form I according to claim 18, wherein said organic solvent is an alcohol.

20. The SAHA Form I according to claim 19, wherein said alcohol is methanol, ethanol or isopropanol.

21. The SAHA Form I according to claim 8, wherein said purification process comprises the step of recrystallizing said crude SAHA from a mixture of an organic solvent and water.

22. The SAHA Form I according to claim 22, wherein said organic solvent is an alcohol.

23. The SAHA Form I according to claim 23, wherein said alcohol is methanol, ethanol or isopropanol.

24. The SAHA Form I according to claim 8, wherein said mixture of organic solvent to water comprises about 1-99% organic solvent and about 99-1% of water.

25. The SAHA Form I according to claim 24, wherein said mixture comprises about 15-85% organic solvent and about 1-15% water.

26. The SAHA Form I according to claim 24, wherein said mixture comprises about 85% organic solvent and about 15% water.

27. The SAHA Form I according to any one of claims 1-26, in plate shaped form.

28. A pharmaceutical composition comprising the SAHA Form I according to any one of claims 1-27 or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier.

29. The composition according to claim 28, in a form suitable for oral administration.

30. The composition according to claim 29, in the form of a tablet.

31. The composition according to claim 29, in the form of a capsule.

32. The composition according to claim 29, contained within a gelatin capsule.

33. The composition according to claim 29, in a form suitable for intravenous administration.

34. The composition according to claim 28, in a form suitable for parenteral, intraperitoneal, intraarterial, transdermal, sublingual, intramuscular, rectal, transbuccal, intranasal, liposomal, vaginal or intraocular administration; or in a form suitable for local delivery by catheter or stent.

35. The composition according to claim 28, in an immediate release dosage form.

36. The composition according to claim 28, in a slow release dosage form.

37. A pharmaceutical composition for oral administration comprising a suberoylanilide hydroxamic acid (SAHA) Form I according to any one of claims 1-26 or a pharmaceutically acceptable salt or hydrate thereof, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate.

38. The composition according to claim 37, comprising:

50-70% by weight of SAHA Form I or a pharmaceutically acceptable salt or hydrate thereof;

20-40% by weight microcrystalline cellulose;

5-15% by weight croscarmellose sodium; and

0.1-5% by weight magnesium stearate.

39. The composition according to claim 37, comprising about 50-200 mg of SAHA Form I.

40. A method of producing a mean plasma concentration of suberoylanilide hydroxamic acid (SAHA) capable of inhibiting a histone deacetylase *in vivo* in a subject over a period of at least two hours following administration, which comprises administering to said subject an effective amount of the pharmaceutical composition according to claim 28.

41. The method according to claim 40, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 2 hours following administration.

42. The method according to claim 40, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 10 hours following administration.

43. The method according to claim 40, wherein said composition provides a mean plasma concentration of SAHA of at least about 2.5 μM over a period of at least 2 hours following administration.

44. The method according to claim 40, wherein said composition is administered orally.

45. The method according to claim 40, wherein said composition is contained within a gelatin capsule.

46. The method according to claim 40, wherein said composition is administered once-daily, twice-daily or three times-daily.

47. The method of claim 40, wherein SAHA is administered to the subject at a total daily dosage of between about 25-4000 mg/m^2.

48. The method according to claim 40, wherein said composition is administered to the subject at a total daily dose of 200 mg.

49. The method according to claim 40, wherein said composition is administered to the subject at a total daily dose of 400 mg.

50. A method of selectively inducing terminal differentiation of neoplastic cells in a subject and thereby inhibiting proliferation of said cells in said subject, said method comprising the step of administering to said subject an effective amount of the pharmaceutical composition according to claim 28.

51. The method according to claim 50, wherein said composition provides a mean plasma concentration of SAHA capable of inhibiting a histone deacetylase *in vivo* in said subject over a period of at least 2 hours following administration.

52. The method according to claim 50, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 2 hours following administration.

53. The method according to claim 50, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 10 hours following administration.

54. The method according to claim 50, wherein said composition provides a mean plasma concentration of SAHA of at least about 2.5 μM over a period of at least 2 hours following administration.

55. The method according to claim 50, wherein said composition is administered orally.

56. The method according to claim 50, wherein said composition is contained within a gelatin capsule.

57. The method according to claim 50, wherein said composition is administered once-daily, twice-daily or three times-daily.

58. The method of claim 40, wherein SAHA is administered to the subject at a total daily dosage of between about 25-4000 mg/m^2.

59. The method according to claim 50, wherein said composition is administered to the subject at a total daily dose of 200 mg.

60. The method according to claim 50, wherein said composition is administered to the subject at a total daily dose of 400 mg.

61. A method of inducing differentiation of tumor cells in a subject having a tumor, said method comprising the step of administering to said subject an effective amount of the pharmaceutical composition according to claim 28.

62. The method according to claim 61, wherein said composition provides a mean plasma concentration of SAHA capable of inhibiting a histone deacetylase *in vivo* in said subject over a period of at least 2 hours following administration.

63. The method according to claim 61, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 2 hours following administration.

64. The method according to claim 61, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 10 hours following administration.

65. The method according to claim 61, wherein said composition provides a mean plasma concentration of SAHA of at least about 2.5 μM over a period of at least 2 hours following administration.

66. The method according to claim 61, wherein said composition is administered orally.

67. The method according to claim 61, wherein said composition is contained within a gelatin capsule.

68. The method according to claim 61, wherein said composition is administered once-daily, twice-daily or three times-daily.

69. The method of claim 61, wherein SAHA is administered to the subject at a total daily dosage of between about 25-4000 mg/m^2.

70. The method according to claim 61, wherein said composition is administered to the subject at a total daily dose of 200 mg.

71. The method according to claim 41, wherein said composition is administered to the subject at a total daily dose of 400 mg.

72. A method of selectively inducing cell growth arrest of neoplastic cells in a subject and thereby inhibiting proliferation of said cells in said subject, said method comprising the step of administering to said subject an effective amount of the pharmaceutical composition according to claim 28.

73. The method according to claim 72, wherein said composition provides a mean plasma concentration of SAHA capable of inhibiting a histone deacetylase *in vivo* in said subject over a period of at least 2 hours following administration.

74. The method according to claim 72, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 2 hours following administration.

75. The method according to claim 72, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 10 hours following administration.

76. The method according to claim 72, wherein said composition provides a mean plasma concentration of SAHA of at least about 2.5 μM over a period of at least 2 hours following administration.

77. The method according to claim 72, wherein said composition is administered orally.

78. The method according to claim 72, wherein said composition is contained within a gelatin capsule.

79. The method according to claim 72, wherein said composition is administered once-daily, twice-daily or three times-daily.

80. The method of claim 72, wherein SAHA is administered to the subject at a total daily dosage of between about 25-4000 mg/m^2.

81. The method according to claim 72, wherein said composition is administered to the subject at a total daily dose of 200 mg.

82. The method according to claim 72, wherein said composition is administered to the subject at a total daily dose of 400 mg.

83. A method of selectively inducing apoptosis of neoplastic cells in a subject and thereby inhibiting proliferation of such cells in said subject, said method comprising the step of administering to said subject an effective amount of the pharmaceutical composition according to claim 28.

84. The method according to claim 83, wherein said composition provides a mean plasma concentration of SAHA capable of inhibiting a histone deacetylase *in vivo* in said subject over a period of at least 2 hours following administration.

85. The method according to claim 83, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 2 hours following administration.

86. The method according to claim 83, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 10 hours following administration.

87. The method according to claim 83, wherein said composition provides a mean plasma concentration of SAHA of at least about 2.5 μM over a period of at least 2 hours following administration.

88. The method according to claim 83, wherein said composition is administered orally.

89. The method according to claim 83, wherein said composition is contained within a gelatin capsule.

90. The method according to claim 83, wherein said composition is administered once-daily, twice-daily or three times-daily.

91. The method of claim 82, wherein SAHA is administered to the subject at a total daily dosage of between about 25-4000 mg/m^2.

92. The method according to claim 83, wherein said composition is administered to the subject at a total daily dose of 200 mg.

93. The method according to claim 83, wherein said composition is administered to the subject at a total daily dose of 400 mg.

94. A method of treating cancer in a subject in need thereof, said method comprising the step of administering to said subject an effective amount of the pharmaceutical composition according to claim 28.

95. The method according to claim 94, wherein said composition provides a mean plasma concentration of SAHA capable of inhibiting a histone deacetylase *in vivo* in said subject over a period of at least 2 hours following administration.

96. The method according to claim 94, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 2 hours following administration.

97. The method according to claim 94, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 10 hours following administration.

98. The method according to claim 94, wherein said composition provides a mean plasma concentration of SAHA of at least about 2.5 μM over a period of at least 2 hours following administration.

99. The method according to claim 94, wherein said composition is administered orally.

100. The method according to claim 94, wherein said composition is contained within a gelatin capsule.

101. The method according to claim 94, wherein said composition is administered once-daily, twice-daily or three times-daily.

102. The method of claim 94, wherein SAHA is administered to the subject at a total daily dosage of between about 25-4000 mg/m^2.

103. The method according to claim 94, wherein said composition is administered to the subject at a total daily dose of 200 mg.

104. The method according to claim 94, wherein said composition is administered to the subject at a total daily dose of 400 mg.

105. A method of selectively inducing terminal differentiation of neoplastic cells and thereby inhibiting proliferation of said cells, said method comprising the step of contacting said cells under suitable conditions with an effective amount of a suberoylanilide hydroxamic acid (SAHA) Form I according to any one of claims 1-27, wherein the amount of SAHA is effective to selectively induce terminal differentiation in said cells.

106. A method of selectively inducing cell growth arrest of neoplastic cells and thereby inhibiting proliferation of said cells, said method comprising the step of contacting said cells under suitable conditions with an effective amount of a suberoylanilide hydroxamic acid (SAHA) Form I according to any one of claims 1-27, wherein the amount of SAHA is effective to selectively induce cell growth arrest in said cells.

107. A method of selectively inducing apoptosis of neoplastic cells and thereby inhibiting proliferation of said cells, said method comprising the step of contacting said cells under suitable conditions with an effective amount of a suberoylanilide hydroxamic acid (SAHA) Form I according to any one of claims 1-27, wherein the amount of SAHA is effective to selectively induce apoptosis in said cells.

108. A process for preparing a suberoylanilide hydroxamic acid (SAHA) Form I comprising the step of recrystallizing a crude preparation of SAHA from an organic solvent or a mixture of an organic solvent and water, with the proviso that the use of acetonitrile alone is excluded.

109. The process according to claim 108, wherein said organic solvent is an alcohol.

110. The process according to claim 109, wherein said alcohol is methanol, ethanol or isopropanol.

111. The process according to claim 108, wherein said process comprises the step of recrystallizing said crude SAHA from an organic solvent.

112. The process according to claim 111, wherein said organic solvent is an alcohol.

113. The process according to claim 112, wherein said alcohol is methanol, ethanol or isopropanol.

114. The process according to claim 108, wherein said process comprises the step of recrystallizing said crude SAHA from a mixture of an organic solvent and water.

115. The process according to claim 114, wherein said organic solvent is an alcohol.

116. The process according to claim 115, wherein said alcohol is methanol, ethanol or isopropanol.

117. The process according to claim 108, wherein said mixture of organic solvent to water comprises about 1-99% of organic solvent and about 99-1% of water.

118. The process according to claim 117, wherein said mixture comprises about 15-85% of organic solvent and about 1-15% water.

119. The process according to claim 118, wherein said mixture comprises about 85% of organic solvent and about 15% water.

120. A method of shrinking tumors in a subject in need thereof, said method comprising the step of administering to said subject an effective amount of the pharmaceutical composition according to claim 28.

121. The method according to claim 120, wherein said composition provides a mean plasma concentration of SAHA capable of inhibiting a histone deacetylase *in vivo* in said subject over a period of at least 2 hours following administration.

122. The method according to claim 120, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 2 hours following administration.

123. The method according to claim 120, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 10 hours following administration.

124. The method according to claim 120, wherein said composition provides a mean plasma concentration of SAHA of at least about 2.5 μM over a period of at least 2 hours following administration.

125. The method according to claim 120, wherein said composition is administered orally.

126. The method of claim 120, wherein SAHA is administered to the subject at a total daily dosage of between about 25-4000 mg/m^2.

127. The method according to claim 120, wherein said composition is administered to the subject at a total daily dose of 200 mg.

128. The method according to claim 120, wherein said composition is administered to the subject at a total daily dose of 400 mg.

129. A method of chemoprevention in a subject in need thereof, said method comprising the step of administering to said subject an effective amount of the pharmaceutical composition according to claim 28.

130. The method according to claim 129, wherein said composition provides a mean plasma concentration of SAHA capable of inhibiting a histone deacetylase *in vivo* in said subject over a period of at least 2 hours following administration.

131. The method according to claim 129, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 2 hours following administration.

132. The method according to claim 129, wherein said composition provides a mean plasma concentration of SAHA of at least about 10 nM *in vivo* for a period of at least 10 hours following administration.

133. The method according to claim 129, wherein said composition provides a mean plasma concentration of SAHA of at least about 2.5 μM over a period of at least 2 hours following administration.

134. The method according to claim 129, wherein said composition is administered orally.

135. The method of claim 129, wherein SAHA is administered to the subject at a total daily dosage of between about 25-4000 mg/m^2.

136. The method according to claim 129, wherein said composition is administered to the subject at a total daily dose of 200 mg.

137. The method according to claim 120, wherein said composition is administered to the subject at a total daily dose of 400 mg.